**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS** **S5**

**PROPRIETARY NAME and dosage form**

**PATRAM** Film-coated tablets

**Read all of this leaflet carefully before you start taking PATRAM Tablets**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PATRAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What PATRAM is and what it is used for
2. What you need to know before you take PATRAM
3. How to take PATRAM
4. Possible side effects
5. How to store PATRAM
6. Contents of the pack and other information

## 1. What PATRAM is and what it is used for

**PATRAM** is indicated for the management of moderate to moderately-severe pain in adults.

**PATRAM** is not recommended for minor pain that may be treated adequately through lesser means.

## 2. What you need to know before you take PATRAM

### You should not take PATRAM

- If you have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) after taking tramadol or paracetamol or any of the other ingredients in PATRAM (listed in section 6).
- if you take other medicines containing paracetamol or tramadol;
- In acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)
- If you are also taking MAO inhibitors (certain medicines used for treatment of depression or Parkinson's disease) or have taken them in the last 14 days before treatment with PATRAM.
- If you suffer from a severe liver disorder.
- If you have epilepsy that is not adequately controlled on your current medicine
- As part of treatment of withdrawal from drugs

- If you had serious head injuries or a brain disease causing pressure on your brain

**Warnings and precautions**

**Take special care with PATRAM**

Do not take more than your recommended dose;

**PATRAM contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately**

Dosages in excess of those recommended may cause severe liver damage and other problems (see possible side effects)

**Tell your doctor:**

- if you have ever had an allergic reaction (characterised by significant skin rash, itching, hives, difficulty breathing, and/or swollen face) while taking codeine or other opioids.
- Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens - Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using PATRAM immediately and contact your doctor.

- If you have liver problems or liver disease or if you notice your eyes and skin turning yellow. This may suggest jaundice or problems with your bile ducts.
- If you have kidney problems
- If you have severe difficulties in breathing for example asthma or severe lung problems
- If you have epilepsy or have already experienced fits or seizures
- If you are taking any other medicine, because taking some medicines together with PATRAM may increase your risk of fits (seizures);
- If you have recently suffered from a head injury, shock or severe headaches associated with vomiting.
- If you are dependent on any medicines including those used to relieve pain, for example morphine or codeine.
- If you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocin, you should not take PATRAM.
- If you have a history of mental health disorder because taking PATRAM may increase your risk of dependence or abuse of the medicine.

If you are going to have an anaesthetic. Tell your doctor or dentist that you are taking PATRAM tablets.

- Do not give PATRAM to a child under 12 years of age;

- Do not give PATRAM to a child under 18 years of age that has just had an operation to remove their tonsils or adenoids.

**Taking PATRAM with food and drink:**

**PATRAM** may be taken with or without food or drink.

**PATRAM** should not be taken with alcohol containing beverages.

**Pregnancy and Breastfeeding:**

Do not take PATRAM if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking PATRAM.

**Driving and using machinery**

PATRAM may make you feel drowsy and this may affect your ability to drive, or use tools and machines, safely.

**Taking other medicines with PATRAM:**

Always tell your healthcare professional if you taking any other medicine. (This includes complementary or traditional medicines).

You must not take PATRAM together with monoamine oxidase inhibitors ("MAOIs") or within 14 days of discontinuation of it. You must also not take PATRAM together with other tramadol or paracetamol containing products. PATRAM must not be taken with alcohol.

PATRAM is not recommended to be taken with the following:

- Carbamazepine (a medicine commonly used to treat epilepsy or some types of pain such as severe pain attacks in the face called trigeminal neuralgia).

- Buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The pain-relieving effect may be reduced.

- Triptans (for migraine) or selective serotonin re-uptake inhibitors, "SSRIs" (for depression).

- Tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine).

- Medicines to treat allergies. You may feel drowsy or feel faint. If this happens, tell your doctor.

- Antidepressants, anaesthetics, neuroleptics (medicines that affect the state of mind).

- The risk of having a fit may increase. Your doctor will tell you whether PATRAM is suitable for you.

- Warfarin or other medicines for blood thinning. The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

## 2. How to take PATRAM TABLETS

Do not share medicines prescribed for you with any other person.

Always take **PATRAM** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for adults and children over 16 years of age is 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day. DO NOT EXCEED THE RECOMMENDED DOSE.

Your doctor will tell you for how long your treatment with PATRAM will last. If you have the impression that the effect of PATRAM is too strong or too weak, tell your doctor or pharmacist

*Patients with impaired kidney or liver function:*

Do not take PATRAM if you have severe liver problems.

Tell your doctor if you have a kidney disorder (a creatinine clearance < 30 mL/min). Do not take more than 2 tablets every 12 hours.

PATRAM is not recommended for children under 16 years of age.

**How and when should you take PATRAM**

The tablets should be swallowed whole with water and may be taken with or without food.

**If you take more PATRAM than you should**

**In the event of overdosage or suspected overdose and even if no symptoms of overdosage are noticeable, you must be taken to the nearest doctor, hospital or Poison Centre immediately.**

Take this leaflet or some tablets with you so your doctor will know what you have taken.

## If you forget to take PATRAM

The pain is likely to return. Do not take a double dose to compensate; just wait for the next dose, and take a normal dose as prescribed by your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 3. Possible side-effects

**PATRAM** Tablets can have side effects.

Not all side effects reported for PATRAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this PATRAM, please consult your doctor, pharmacist or other healthcare professional for advice.

**Very serious side effects:**

If any of the following happens, stop taking PATRAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A skin rash (indicating an allergic reaction), sudden swelling of the face and neck, difficulty breathing or drop of blood pressure and fainting.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to PATRAM. You may need urgent medical attention or hospitalisation.

**Serious side effects**

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following: The following side effects occur frequently**:**

- Yellow skin and eyes (hepatitis)
- Irregular heartbeat that is much rapid and more pronounced than usual, increased blood pressure, pain in the chest
- Elevated liver enzymes, resulting in abdominal pain, dark urine, pale stools, weakness, fatigue.
- Feeling faint when getting up from lying down or sitting position, trouble performing routine tasks
- Difficulty swallowing, blood in stools
- Addiction

- Blurred vision

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- Confusional state, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits).
- Dizziness, excessive sleepiness, fatigue, feeling weak
- Headache, trembling.
- Nausea, vomiting, constipation, dry mouth, diarrhoea, stomach pain, indigestion, stomach gas.
- Loss of appetite;
- Itching, rash, swelling of the tongue.
- Loss of coordination, fits, abnormal muscle tension

*Less frequent side effects*

- Itching, increased sweating,
- Shivering, hot flushes.
- Depression, seeing, hearing, smelling, tasting or imagining things, nightmares.
- Involuntary muscular contractions, feeling pins and needles (tingling or prickling sensation), loss of memory.
- Ringing in the ear.
- Rapid, strong, or irregular heartbeat, very fast heartbeat, dysrhythmia.

- Weight decrease
- Chills.
- Chest pain.
- Problems with urination.
- Difficulty breathing.
- Increase in blood pressure
- Low blood sugar.
- Drug dependence.
- Mental confusion and emotional disruption.
- Convulsions, fainting, speech disorders.
- Slurred speech, stumbling, convulsions, syncope, speech disorders.
- Vision blurred, constriction of the pupil (miosis).
- Excessive dilation of the pupils (mydriasis).

In addition, the following side effects have been reported by people using medicines that contain only tramadol or only paracetamol:

- Feeling faint when getting up from a lying or sitting position, slow heart rate, fainting.
- Changes in appetite.
- Muscle weakness, slower or weaker breathing.
- Mood changes, changes in activity, changes in perception.
- Worsening of existing asthma.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of PATRAM

## 4. STORING AND DISPOSING OF PATRAM

Store at or below 25 °C. Protect from light and moisture.

Do not remove the blister strips from the cartons until required for use.

**KEEP OUT OF REACH OF CHILDREN**

Do not use the PATRAM Tablets after the expiry date which is printed on the carton and the edge of the blister.

The expiry date refers to the last day of that month.

## 5. PRESENTATION OF PATRAM

Each carton contains 100 tablets packed as 10 x 10 PVC/PVDC-Aluminum blister strips.

## 6. IDENTIFICATION OF PATRAM

White to off-white, round biconvex film-coated tablets plain on both the surfaces.

## 9. REGISTRATION NUMBER

46/2.9/0449

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1

Roodepoort, 1724

South Africa

## 11. DATE OF PUBLICATION

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**PASIËNTINLIGTINGSTUK**

**SKEDULERINGSTATUS S5**

**HANDELSNAAM en doseervorm**

**PATRAM**

(Filmbedekte tablette)

**Tramadolhidrochloried 37.5 mg en parasetamol 325 mg**

**Suikervry**

**Lees die hele inligtingstuk noukeurig deur voordat jy begin om PATRAM tablette te neem**

- Hou hierdie inligtingstuk. Jy sal dit moontlik weer moet lees.
- Vra asseblief jou dokter of apteker as jy verdere vrae het.
- Patram is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met enige ander persoon deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome soortgelyk aan joune is.

**Wat is in hierdie inligtingstuk**

1. Wat PATRAM is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy PATRAM neem
3. Hoe om PATRAM te neem
4. Moontlike newe-effekte
5. Hoe om PATRAM te bewaar
6. Inhoud van die verpakking en ander inligting

## 1. Wat PATRAM is en waarvoor dit gebruik word

PATRAM word aangedui vir die beheer van matige tot matig-ernstige pyn by volwassenes. PATRAM word nie aanbeveel vir ligte pyn wat voldoende met ander middels behandel kan word nie.

## 2. Wat jy moet weet voordat jy PATRAM neem

**Moenie PATRAM neem nie**

- As jy ‘n allergiese reaksie gehad het (byvoorbeeld veluitslag, swelling van die gesig, hyging of sukkel met asemhaling) nadat tramadol of parasetamol geneem is of enige van die ander bestanddele in PATRAM (gelys in afdeling 6)
- As jy ‘n kombinasie van enige van die volgende simptome ervaar of voorheen ervaar het: uitslag, rooi vel, blasievorming op die lippe, oë en mond, velafskilfering, hoë koors, griepagtige simptome, verhoogde vlakke van lewerensieme waargeneem in bloedtoetse en ‘n toename in ‘n tipe witbloedsel (eosinofilie) en vergrote limfnodes (tekens van ernstige velreaksies, sien ook afdeling 4) staak onmiddellik die gebruik van PATRAM en kontak jou dokter
- As jy ander medisyne gebruik wat parasetamol of tramadol bevat
- In akute poisoning with vergiftiging met alkohol, slaappille, pynverligters of ander psigotropiese medisyne (medisyne wat jou gemoed en emosies kan affekteer)

- As jy ook mono-amienoksidase remmers gebruik (sekere medisyne wat gebruik word vir die behandeling van depressie of Parkinson se siekte) of dit die afgelope 14 dae voor behandeling met PATRAM geneem het
- As jy aan ‘n matige tot ernstige lewerversteuring ly
- As jy epilepsie het wat nie voldoende op jou huidige medikasie gekontroleer word nie.
- As deel van behandeling vir onttrekking van dwelmmiddels
- As jy ernstige hoofbeserings of ‘n breinsiekte gehad het wat drukking op die brein veroorsaak

**Waarskuwings en voorsorgmaatreëls**

**Tref spesiale voorsorg met PATRAM:**

Moenie meer as jou aanbevole dosis neem nie:

**PATRAM bevat parasetamol wat in oordosis noodlottig kan wees. In die geval van oordosering of vermoedelike oordosering en nieteenstaande die feit dat die persoon asimptomaties kan wees, moet die naaste dokter, hospitaal of gifbeheersentrum onmiddellik gekontak word.**

Groter dosisse as dit wat aanbeveel word, kan ernstige lewerskade en ander probleme veroorsaak (sien moontlike newe-effekte)

**Lig jou dokter of professionele gesondheidsorgverskaffer in:**

- As jy al ooit ‘n allergiese reaksie gehad het (gekenmerk deur betekenisvolle veluitslag, jeuk, galbulte, sukkel om asem te haal, en/of geswelde gesig) terwyl jy kodeïen of ander opioïede neem.

- As jy lewerprobleme of lewersiekte het of as jy opmerk dat jou oë en vel geel verkleur. Dit kan ‘n aanduiding wees van geelsug of probleme met jou galbuise.
- As jy nierprobleme het
- As jy ernstige probleme met asemhaling het, byvoorbeeld asma of ernstige longprobleme
- As jy epilepsie het of alreeds aanvalle of toevalle ervaar het
- As jy enige ander medisyne neem, omdat die gebruik van sommige medisyne saam met PATRAM jou risiko van aanvalle (toevalle) kan verhoog
- As jy onlangs ‘n slagoffer van ‘n hoofbesering was, skok of ernstige hoofpyne gehad het geassosieer met braking.
- As jy afhanklik is van ander medisyne, insluitend dié wat gebruik word om pyn te verlig, byvoorbeeld morfien of kodeïen.
- As jy ander medisyne neem wat buprenorfien, nalbufien of pentasosien bevat om pyn te behandel, moet jy nie PATRAM neem nie.
- As jy ‘n geskiedenis van ‘n geestessiekte versteuring het, omdat die gebruik van PATRAM jou risiko van afhanklikheid of misbruik kan verhoog.
- As jy ‘n narkosemiddel gaan ontvang. Lig jou dokter of tandarts in dat jy PATRAM tablette neem.
- Moenie PATRAM aan ‘n kind onder die ouderdom van 12 jaar gee nie.
- Moenie PATRAM aan ‘n kind onder die ouderdom van 18 jaar gee wat pas ‘n operasie om mangels of adenoïede te verwyder, gehad het nie.

**Ander medisyne saam met PATRAM:**

Lig jou professionele gesondheidsorgverskaffer altyd in as jy enige ander medisyne gebruik. (Dit sluit aanvullende of tradisionele medisyne in).

Jy moet nie PATRAM saam met mono-amienoksidase remmers (“MAOIs”) of binne 14 dae ná onttrekking daarvan, gebruik nie. Jy moet ook nie PATRAM saam met enige ander produkte wat tramadol of parasetamol bevat, gebruik nie.

PATRAM word nie aanbeveel om saam met die volgende geneem te word nie:

- Karbamasepien (‘n medisyne wat algemeen gebruik word om epilepsie te behandel of sommige tipes pyn soos ernstige pynaanvalle in die gesig wat bekend staan as trigeminale neuralgie).

- Buprenorfien, nalbufien of pentasosien (opioïed-tipe pynstillers). Die pynstillende effek kan minder wees.

- Triptane (vir migraine) of selektiewe serotonien-heropname inhibeerders, “SSRIs” (vir depressie).

- Susmiddels, slaappille, ander pynverligters soos morfien en kodeïen (ook soos hoesmedisyne).

- Antidepressante, narkosemiddels, neuroleptika (medisyne wat die gemoedstoestand affekteer).

- Die risiko om ‘n toeval te kry, kan verhoog. Jou dokter sal jou inlig of PATRAM vir jou geskik is.

- Warfarien of ander medisyne vir bloedverdunning. Die doeltreffendheid van sulke medisyne kan verander word en bloeding kan voorkom. Enige verlengde of onverwagse bloeding moet onmiddellik aan jou dokter gerapporteer word.

**PATRAM saam met voedsel en drinkgoed**

PATRAM kan met of sonder voedsel of drinkgoed geneem word.

Moenie alkohol tydens behandeling met PATRAM gebruik nie, aangesien die effekte van PATRAM en alkohol mekaar kan intensifeer.

**Swangerskap, borsvoeding en fertiliteit:**

Moenie PATRAM neem as jy swanger is of borsvoed nie.

Indien jy swanger is of jou baba borsvoed, moet jy asseblief jou dokter, apteker of ander professionele gesondheidsorgdeskundige raadpleeg vir advies voordat jy PATRAM neem.

**Bestuur en gebruik van masjinerie**

Dit is nie altyd moontlik om te voorspel tot watter mate PATRAM met jou daaglikse aktiwiteite sal inmeng nie.

Jy moet seker maak dat jy nie betrokke raak in die bogenoemde aktiwiteite totdat jy seker is tot watter mate PATRAM jou sal affekteer nie.

PATRAM kan jou lomerig laat voel en dit kan jou vermoë om te bestuur of apparaat en masjinerie veilig te gebruik, affekteer.

**PATRAM bevat:**

Voorafgegelatiniseerde stysel (Starch 1500), mieliestysel, natriumstysel-glikolaat (Tipe A); kolloïdale silikondioksied (aerosil 200); magnesiumstearaat.

Opadry wit # (Y-1-7000) bestaande uit: hipromellose; titaandioksied; poliëtileenglikool.

## 3. Hoe om PATRAM tablette te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem PATRAM altyd presies soos wat jou dokter dit voorgeskryf het. Jy moet met jou dokter of apteker kontroleer as jy onseker is.

Die normale dosis vir volwassenes en kinders bo die ouderdom van 16 jaar is 1 of 2 tablette elke 4 tot 6 uur soos nodig vir die verligting van pyn tot ‘n maksimum van 8 tablette per dag.

MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE.

Jou dokter sal vir jou sê hoe lank jou behandeling met PATRAM sal duur. Lig jou dokter of apteker in as jy onder die indruk is dat die effek van PATRAM te sterk of te swak is.

*Pasiënte met ingekorte nier- of lewerfunksie:*

Moenie PATRAM neem as jy matige tot ernstige lewerprobleme het nie.

Lig jou dokter in as jy ‘n nierversteuring (‘n kreatinienopruiming < 30 mL/min) het. Moenie meer as 2 tablette elke 12 uur neem nie.

PATRAM word nie aanbeveel by kinders onder die ouderdom van 16 jaar nie.

**Hoe en wanneer moet PATRAM geneem word**

Die tablette moet heel ingesluk word met water en kan met of sonder voedsel geneem word.

**As jy meer PATRAM geneem het as wat jy behoort te neem**

**In die geval van oordosering of vermoedelike oordosering en selfs as geen simptome van oordosering merkbaar is nie, moet jy onmiddellik na die naaste dokter, hospitaal of gifbeheersentrum geneem word.**

**Neem hierdie inligtingstuk en sommige tablette saam met jou sodat jou dokter kan weet wat jy geneem het.**

**As jy vergeet het om PATRAM te neem**

Die pyn sal waarskynlik terugkeer. Moenie ‘n dubbele dosis neem om te kompenseer nie; wag net vir die volgende dosis en neem ‘n normale dosis soos wat jou dokter voorgeskryf het.

**As jy ophou om PATRAM te neem**

Onttrekkingsimptome kan voorkom indien PATRAM skielik gestaak word. Jy kan angstigheid, senuweeagtige opgewondenheid, sukkel om te slaap, buitensporige abnormale bewegings, bewing en gastro-intestinale simptome ervaar.

Ander simptome wat selde waargeneem word wanneer tramadolhidrochloried, soos bevat in PATRAM, skielik gestaak word, sluit in: paniekaanvalle, erge angstigheid, hallusinasies, tintelende of prikkelende sensasie en suising in die ore.

Vra jou dokter of apteker as jy verdere vrae het oor die gebruik van hierdie produk.

## 4. Moontlike newe-effekte

PATRAM tablette kan newe-effekte hê.

Nie alle newe-effekte wat vir PATRAM aangemeld word, is in hierdie inligtingstuk opgeneem nie. Indien jou algemene gesondheid versleg of as jy enige ongewenste effekte ervaar terwyl jy PATRAM neem, moet jy asseblief jou dokter, apteker of ander professionele gesondheidsorgverskaffer raadpleeg vir advies.

**Baie ernstige newe-effekte:**

Indien enige van die volgende gebeur, staak die gebruik van PATRAM en lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- ‘n Veluitslag (wat dui op ‘n allergiese reaksie), skielike swelling van die gesig en nek, moeilike asemhaling of val in bloeddruk en floute.

Hierdie is almal baie ernstige newe-effekte. As jy dit ervaar het, kon jy ‘n ernstige allergiese reaksie teen PATRAM gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

**Ernstige newe-effekte**

Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:

Die volgende newe-effekte kom dikwels voor:

- Vergeling van die vel en oë (hepatitis)
- Onreëlmatige hartklop wat baie vinniger en meer uitgesproke as normaalweg is, verhoogde bloeddruk, pyn in die borskas
- Verhoogde lewerensieme wat lei tot abdominale pyn, donker urine, bleek stoelgang, swakheid, moegheid.
- Voel asof jy flou gaan word as jy opstaan vanaf ‘n lêende of sittende posisie, sukkel om roetine take uit te over
- Moeilik om te sluk, bloed in stoelgang
- Verslawing
- Dowwe visie

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

*Dikwelse newe-effekte:*

- Verwarde toestand, slaapversteurings, gemoedsveranderinge (angstigheid, senuweeagtigheid, opgeruimde gevoel).
- Duiseligheid, oormatige slaperigheid, moegheid, voel swak.
- Hoofpyn, bewerigheid.

- Naarheid, braking, hardlywigheid, droë mond, diarree, maagpyn, slegte spysvertering, winderigheid in die maag.
- Verlies aan aptyt.
- Jeuk, uitslag, swelling van die tong.
- Verlies aan koördinasie, toevalle, abnormale spierspanning

*Minder dikwelse newe-effekte*

- Jeuk, verhoogde sweet.
- Bewerig, warmgloede.
- Depressie, sien, hoor, ruik, proe of verbeel dinge, nagmerries.
- Onwillekeurige spiersametrekkings, gevoel van spelde en naalde (tintelende of prikkelende sensasie), geheueverlies.
- Suising in die oor.
- Vinnige, sterk of onreëlmatige hartklop, baie vinnige hartklop, disritmie.
- Gewigsverlies.
- Koue rillings.
- Borskaspyn.
- Probleme met urinering.
- Moeilike asemhaling.
- Verhoogde bloeddruk.
- Lae bloedsuiker.
- Geneesmiddelafhanklikheid.
- Geestelike verwarring en emosionele ontwrigting.
- Konvulsies, floute, spraakversteurings.
- Sleepspraak, stuikeling, konvulsies, floute, spraakversteurings.
- Dowwe visie, sametrekking van die pupil (miose).
- Oormatige dilatering van die pupille (midriase)

- Metaboliese asidose (naarheid, braking, moegheid, verwarring, vinnige asemhaling)

Die volgende newe-effekte is bykomend aangemeld by persone wat mediyne gebruik het wat slegs tramadol of slegs parasetamol bevat het:

- Voel asof jy flou gaan word as jy opstaan vanaf ‘n lêende of sittende posisie, stadige hartritme, floute.
- Veranderinge in aptyt.
- Spierswakheid, stadiger of swakker asemhaling.
- Gemoedsveranderinge, veranderinge in aktiwiteit, veranderinge in waarneming.
- Verergering van bestaande asma.

As jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.

**Aanmelding van newe-effekte**

Lig jou dokter, apteker of verpleegkundige in as jy newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (whoumc.org) wat aanlyn op SAHPRA se webwerf beskikbaar is.

Vermoedelike newe-effekte kan ook direk aan die houer van die registrasiesertifikaat *via* e-pos aangemeld word: pharmacovigilance.africasme@sunpharma.com of tel: +27(0) 643 2000

Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van PATRAM te verskaf.

## 5. Hoe om PATRAM te bewaar

Bewaar alle medisyne buite die bereik van kinders.

Bewaar by of onder 25 °C. Beskerm teen lig en vog.

Moenie die stulpstroke uit die karton verwyder tot benodig vir gebruik nie.

Moenie die PATRAM tablette ná die vervaldatum wat op die karton en op die kant van die stulpstrook gedruk is, gebruik nie.

Die vervaldatum verwys na die laaste dag van daardie maand.

## 6. Inhoud van die verpakking en ander inligting

### Wat PATRAM bevat

Die aktiewe bestanddele is tramadol en parasetamol

Die ander bestanddele is voorafgegelatiniseerde stysel (Starch 1500), mieliestysel, natriumstysel-glikolaat (Tipe A); kolloïdale silikondioksied (aerosil 200); magnesiumstearaat.

Opadry wit # (Y-1-7000) bestaande uit: hipromellose; titaandioksied; poliëtileenglikool.

### Hoe PATRAM lyk en inhoud van die verpakking

Wit tot naaswit, ronde bikonvekse filmbedekte tablette met skoon oppervlaktes op albei kante.

100 tablette per karton, 10 tablette per stulpstrook van PVC/PVDC-Aluminium. Die stulpstroke word in ‘n karton verpak saam met ‘n inligtingstuk.

**Houer van die Registrasiesertifikaat**

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**Hierdie inligtingstuk was laas hersien op**

04 Februarie 2026

**Registrasienommer**

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